

### REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed September 1, 2006 ("Office Action"). Claims 72, 74-110, 112, and 114-119 are pending in the application. Claims 72, 99, 107, 117, and 118 are currently amended. Support for the subject matter of the currently amended claims may be found, for instance, at page 14, lines 15-25 of the specification as originally filed. Accordingly, no new matter is included in the originally filed claims. Applicant notes with appreciation the allowance of claims 77-79, 89, 93, and 100 as well as the indication of allowability of the subject matter of claim 102. Applicant respectfully requests reconsideration as to the rejection of claims 72, 74-76, 80-88, 90-92, 94-99, 101, 103-110, 112 and 114-119.

### Anticipation -- 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Manual of Patent Examining Procedure § 2131 (8th ed., rev. 5, Aug. 2006) (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The Office Action rejects claims 72, 74, 82, 88, 90, 99, 101, 107, 112, 114, and 117-119 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,587,705 ("Kim").

Kim discloses a biosensor with an automated sampling system that "transdermally extracts the sample in a continual manner over the course of a 1-24 hour period, or longer, using sonophoresis." Kim, col. 17, ll. 34-37. According to Kim, "[t]he source of ultrasonic radiation provides ultrasound frequencies of greater than about 10 MHz, preferably in the range of about 10 to 50 MHz, most preferably in the range of about 15 to 25 MHz." Kim, col. 17, 40-44.

The invention of claims 72, 99, 107, 117, and 118 requires "a low frequency ultrasound transducer for increasing the permeability of an area of skin, said low frequency ultrasound transducer adapted to operate at a frequency of less than 2.5 MHz" or a step of "increasing a permeability level of an area of skin by applying low frequency ultrasound forces to said area, said low frequency ultrasound forces having a frequency of less than 2.5 MHz." As described in the specification, "application of ultrasound having a particular frequency will disorganize the

lipid bilayer in the skin and thus increase the permeability of the skin.” Specification, ¶¶ bridging pages 14-15. Application of low frequency ultrasound decreases “the required intensity of the driving force” to transport analytes across the skin. Specification, ¶¶ bridging pages 14-15. Thus, the invention of claims 72, 99, 107, 117, and 118 requires application of low frequency ultrasound followed by extraction, whereas Kim merely discloses extraction using ultrasound having frequencies of greater than 10 MHz as the transport force.

As discussed above, anticipation requires that a single prior art reference teach every claim limitation. Since Kim fails to teach every limitation of claims 72, 99, 107, 117, and 118, Kim fails to anticipate such claims. Claims 74, 82, 88, 90, 101, 112, 114, and 119 depend from and incorporate the limitations of independent claims 72, 99, 107, 117, and 118. Accordingly, the rejection of claims 72, 74, 82, 88, 90, 99, 101, 107, 112, 114, and 117-119 under 35 U.S.C. § 102(e) as being anticipated by Kim should be withdrawn.

### **Obviousness -- 35 U.S.C. § 103**

The Office Action rejects claims 72, 74-76, 82, 83, 90, 97, 101, 107, 112, and 114 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,009,343 (“Shain”) in view of Kim.

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so.” M.P.E.P. § 2143.01; see also In re Lee, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002). “The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure.” M.P.E.P. § 2143 (citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Shain teaches enhanced transdermal transport of fluid using a vacuum. Shain teaches applying ultrasound to the skin of an animal and extracting fluid using a vacuum. As noted by the examiner, Shain fails to teach continuous glucose monitoring as required by the claims. That is, the vacuum extraction of Shain is not a continuous extraction process. As such, Shain fails to suggest a way of increasing the permeability of skin in preparation for a continuous analyte monitoring process.

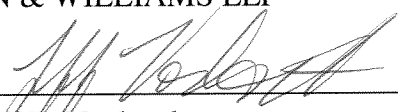
The examiner cites Kim as disclosing continuous analyte monitoring. However, as discussed above, Kim fails to disclose low frequency ultrasound followed by continuous analyte monitoring. Kim, instead, discloses the use of higher frequency ultrasound (i.e., greater than 10 MHz) applied during the extraction step. The combined teachings of Shain and Kim fail to teach or suggest the claimed invention. Specifically, neither Kim nor Shain suggests that a step of applying low frequency ultrasound would provide any benefit in a step of increasing the permeability of skin prior to extraction for continuous analyte monitoring. Accordingly, the rejection of claims 72, 74-76, 82, 83, 90, 97, 101, 107, 112, and 114 under 35 U.S.C. § 103(a) as being unpatentable over Shain in view of Kim should be withdrawn.

Applicant submits that this response addresses all of the issues raised in the Office Action. Applicant therefore submits that claims 72, 74-110, 112, and 114-119 are in condition for allowance and notice to that effect is hereby solicited. Should any issues remain to be discussed in this application, the Examiner is invited to contact the undersigned by telephone.

In the event any variance exists between the amount authorized to be charge to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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